K071904

OCT 25 2007

SECTION 11: PREMARKET NOTIFICATION [510(K)] SUMMARY

Date: June 7, 2007

Applicant: Carleton Life Support Systems, Inc.
2734 Hickory Grove Road
Davenport, IA 52804

Phone: 563-383-6299
FAX: 563-383-6107

Contact: Gary Byrd, Medical Oxygen Engineering Manager

Trade Name: Deployable Oxygen Generation System – Medium (DOGS-M)

Common Name: Oxygen Concentrator

Classification Name: Generator, Oxygen, Portable

Establishment Registration Number: 3002840531

Legally Marketed Device to which Substantial Equivalence is claimed: Deployable Oxygen Concentration System (DOCS) developed by Pacific Consolidated Industries and cleared under submittal K020330.

Description

The Deployable Oxygen Generation System – Medium (DOGS-M) is a point of use oxygen generation system designed to meet the needs of the Air Force for ground based medical support. The DOGS-M consists of an oxygen generation system, a low pressure oxygen compressor, high pressure oxygen compressor, cylinder evacuation pump and integral back up oxygen storage cylinders in a single module. The oxygen generation system uses an integral air compressor and Pressure Swing Adsorption (PSA) technology to separate up to 120 liters per minute of oxygen meeting the requirements of USP93% from ambient air. The high pressure compressor is designed to charge cylinders to 2250 psig at approximately 60 liters per minute. To insure that there are no contaminants in the cylinders prior to filling, the system is provided with an evacuation pump that can evacuate an H cylinder down to 25 inches mercury in less than 10 minutes.

Indications for Use

The DOGS-M system is intended to provide supplemental oxygen enriched gas to patients who may have difficulty extracting oxygen from air that they breathe. The system may be used to provide medical support to the full spectrum of deployed scenarios including wartime operations, deterrence and contingency operations.

peacetime engagement, crisis response and humanitarian relief operations by trained military personnel.

The DOGS-M has the capability to supply pressurized oxygen to fill gas cylinders that can be transported to remote locations away from the DOGS-M system or to fill cylinders for patient ambulatory use.

The oxygen supplied by the DOGS-M is supplemental and is not considered to be life supporting or life sustaining.

This device is not intended to be used in the presence of flammable anesthetics nor is it intended to be sterilized.

There are no contraindications.

Technological Summary

The primary function of the DOGS-M is to provide supplemental oxygen for military medical applications. The DOGS-M uses the same technology, the pressure swing adsorption process, as the predicate device to produce USP 93% oxygen. Both the predicate device and the DOGS-M use similar means to compress the gas to 100 psig for low pressure applications and to 2250 psig for storage in cylinders. The technological characteristics of the device and its intended use to supply supplemental oxygen are basically the same as the predicate device and raise no new questions of safety and effectiveness.

The primary difference between the DOGS-M and the predicate device is in the smaller size, lower weight and power requirements with a corresponding reduction in output capacity.

Performance

Non-clinical bench testing by Carleton Life Support Systems, Inc. verified that the system is capable of producing up to 120 lpm of of USP 93% oxygen at pressures of 100 psig and charging cylinders up to 2250 psig. Independent laboratory testing also verified that oxygen purity was in accordance with USP 93% and that total gaseous hydrocarbons and halogenated hydrocarbons and particulates were below accepted standards.

Conclusions

Based upon the testing and analysis provided, the DOGS-M is substantially equivalent to the predicate device DOCS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2007

Mr. Gray Byrd
Mechanical Engineering Manager
Carleton Life Support Systems, Incorporated
2734 Hickory Grove Road
Davenport, Iowa 52804-1299

Re: K071904
Trade/Device Name: Deployable Oxygen Generation System-Medium (DOGS-M)
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: August 7, 2007
Received: October 16, 2007

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071904

Device Name: Deployable Oxygen Generation System – Medium (DOGS-M)

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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